

# FY22 Q1 Registration Review FRNs

**FRN #1**, FRL TBD (Not submitted yet): Contains all chemicals in Preliminary Work Plan table. Timing: December 2021

<b>Preliminary Work Plan (PWP)</b> (Red = AA briefing & fact sheet, Orange = Program review & fact sheet, Black = Summary)	
Antimicrobials:	Pelargonic acid, Capric acid, Caprylic acid, and Fatty acid monoesters** <sup>1</sup>
Conventionals:	Cyflufenamid; Fluopyram; Pyroxasulfone
Biopesticides:	None

\*\*Dual Use antimicrobial/biopesticide

<sup>1</sup> Combined PWP/PID. Summary in PID section

**FRN #2**, FRL TBD (Not submitted yet): Contains all chemicals in Draft Risk Assessments table. Timing: December 2021

<b>Draft Risk Assessments (DRAs)</b> (Red = AA briefing & fact sheet, Orange = Program review & fact sheet, Black = Summary)	
Antimicrobials:	1,3 PAD (1,3-Propanediamine, N-(3-aminopropyl)-N-dodecyl-)
Conventionals:	None
Biopesticides:	None

\*Dual use conventional/antimicrobial; \*\* FWP publishing with DRAs

**FRN #3**, FRL TBD (Not submitted yet): Contains all chemicals in Proposed Interim Decisions table. Timing: December 2021

<b>Proposed Interim Decisions (PIDs)</b> (Red = AA briefing & fact sheet, Orange = Program review & fact sheet, Black = Summary)	
Antimicrobials:	Pelargonic acid, Capric acid, Caprylic acid, and Fatty acid monoesters** <sup>2</sup> ; Dimethoxane
Conventionals:	Dithiocarbamates (Ferbam, Thiram, Ziram*); Iprodione
Biopesticides:	Laminarin <sup>2</sup> ; Linalool <sup>2</sup>

\*Dual use conventional/antimicrobial; \*\*Dual Use antimicrobial/biopesticide

<sup>1</sup> Combined DRA/PID. Summary in the PID section.

<sup>2</sup> Combined PWP/PID. Summary in PID section.

**FRN #4**, FRL TBD (Not submitted yet): Contains all chemicals in Interim Decisions table. Timing: December 2021

<b>Interim Decisions (IDs) and Case Closures</b> (Red = AA briefing & fact sheet, Orange = Program review & fact sheet, Black = Summary)	
Antimicrobials:	Pentachlorophenol; Chromated Arsenicals & Dichromic Acid; Creosote
Conventionals:	Amitraz; Difenconazole; Fenbuconazole; Isoxaflutole; Mesotrione; Metaldehyde; Oxyfluorfen; Sodium Cyanide, Sodium Fluoroacetate; Rotenone; Spiromesifen; Tembotrione; Topramezone
Biopesticides:	Cinnamaldehyde; Farnesol and Nerolidol; <i>Nosema locustae</i> ; <i>Ulocladium oudemansii</i> (U3 Strain)

\*Dual use conventional/antimicrobial; \*\*Dual Use antimicrobial/biopesticide; \*\*\*Case Closure Memo

## Endangered Species Assessment Determinations\*

<b>ESA Determinations</b>	
Antimicrobials:	None
Conventionals:	
Amitraz	ID with No Effect determination

ESA Determinations	
Sodium Cyanide	Amended IDs with No Effect/Not Likely Adversely Affect determinations. Worked with FWS and USDA APHIS to revise label language to achieve NLAA and complete consultation informally (i.e., FWS will not need to do a predacide biological opinion).
Sodium Fluoroacetate	
Biopesticides:	
Cinnamaldehyde	ID with No Effect determination
Farnesol and Nerolidol	ID with No Effect determination
<i>Nosema locustae</i>	ID with No Effect determination
<i>Ulocladium oudemansii</i> (U3 Strain)	ID with No Effect determination

## **Q1 AD/Antimicrobial Use PWP Fact Sheets**

**None.**

## **Q1 AD/Antimicrobial Use PWP Summaries**

**See the AD PID summaries for the combined Pelargonic acid, Capric acid, Caprylic acid, and Fatty acid monoesters PWP/PID.**

## **Q1 BPPD/Biopesticide Use PWP Fact Sheets**

**None.**

## **Q1 BPPD/Biopesticide Use PWP Summaries**

**None.**

# Q1 PRD/Conventional Use PWP Fact Sheets

None.

## Q1 PRD/Conventional Use PWP Summaries

### Cyflufenamid

Release Preliminary Work Plan for second cycle of registration review. Cyflufenamid is a phenyl acetamide fungicide that is registered for use in post-emergence control of powdery mildews on agricultural crops and ornamentals. The Agency completed a combined draft human health risk assessment and scoping document for registration review. The draft human health risk assessment did not identify any risks of concern. EPA does not anticipate any further updates to the human health risk assessment for registration review. The Agency anticipates conducting an updated ecological risk assessment after receiving additional toxicity data on aquatic and terrestrial invertebrates and fully assessing the potential ecological risk for cyflufenamid. All other taxa have no risks of concern and will not need to be reassessed, such that the draft risk assessment will rely on the conclusions of these taxa from past assessments. ***Anticipated stakeholder reaction:*** Minimal stakeholder reaction is anticipated.

### Fluopyram

Release Preliminary Work Plan for first cycle of registration review. Fluopyram is a broad-spectrum fungicide and nematicide with preventative, systemic, and curative properties labeled for the control and suppression of crop diseases, including Ascomycetes, leaf spots, molds, scab, Alternaria, Septoria, Monilinia, Botrytis, Sclerotinia, and powdery mildews. Fluopyram is in the pyridinyl ethylbenzimidazole group and is a Succinate Dehydrogenase Inhibitor (SDHI). Fluopyram is registered for use on a wide variety of crops including tree nuts, fruits, tree fruits, and berries, root tubers and corms, legumes, and leafy vegetables and includes non-agricultural uses on Christmas tree plantations, ornamentals and turf. Products can be applied as aerial, banded, banded in-furrow, broadcast, chemigation, ground, spot treatment, and as a seed treatment.

Previous human health risk assessments showed no risks of concern. The Agency has determined that there are no toxicological, residue chemistry, occupational or residential exposure data gaps. EPA anticipates conducting an updated dietary assessment, occupational and residential exposure assessments, spray drift assessment, and an aggregate assessment.

Previous environmental risk assessments have shown chronic risks to birds and mammals for spray applications, and acute and chronic risks to birds and mammals for seed treatments. The Agency anticipates conducting an updated ecological risk assessment after receiving additional toxicity data on terrestrial invertebrates to fully assess the potential ecological risks from fluopyram. There are outstanding data for chronic estuarine and marine invertebrates and fish, with uncertainty how the submission of these data would alter risk conclusions. ***Anticipated stakeholder reaction:*** Minimal stakeholder reaction is anticipated.

### Pyroxasulfone

Release Preliminary Work Plan for first cycle of registration review. Pyroxasulfone is a selective herbicide in the pyrazole class. It is used to control a broad spectrum of annual grasses, sedges, and annual broadleaf weeds on agricultural crops, fallow land, non-crop areas, orchards, and vineyards.

The Agency anticipates conducting an updated draft human health risk assessment and currently does not have any outstanding data requirements or call-ins. The assessment will include spray drift and volatilization language, and there is currently a pending PRIA action on ornamentals that may affect the need for a dislodgeable foliar residue study. Previous human health risk assessments identified inhalation risks of concern for mixer-loaders during aerial applications.

The Agency anticipates conducting an updated ecological risk assessment after receiving additional toxicity data on terrestrial invertebrates to fully assess the potential ecological risk for pyroxasulfone. With the exception for potential risks to mammals and birds on a chronic bases, and potential risks to listed terrestrial monocot plants in semi-aquatic areas, and aquatic plants, there are generally no risks of concern for exposures to terrestrial and aquatic organisms. Risks to vascular and non-vascular plants is expected as pyroxasulfone is an herbicide. ***Anticipated stakeholder reaction:*** Minimal stakeholder reaction is anticipated.

# Q1 AD/Antimicrobial Use DRA Fact Sheets

## 1,3-Propanediamine, N-(3-aminopropyl)-N-dodecyl- (1,3-PAD)

### Current Status

- There are two registered end-use products that contain 1,3-PAD.
- 1,3-PAD is registered for use in poultry and animal housing facilities, restaurants, beverage and food processing plants, and schools where it is used to sanitize non-food contact surfaces such as floors and walls and to control fruit flies in floor and sink drains, as well as for use in metalworking fluids (MWFs) and oil field flood water systems.
- DRA was signed on November 2, 2021

### Human Health Risk Assessment Conclusions

- Dietary:
  - Dietary exposures from food are not anticipated because the only product that may have had food exposures was cancelled in 2017.
  - Drinking water exposures are anticipated from the use in MWF. These exposures were assessed using a wastewater treatment plant removal rate of 52%. There are no risks of concern for all population subgroups.
- Residential exposures:
  - Residential exposures are not anticipated because the products are not intended for purchase and use by residential handlers and they are not used by professional applicators in residential areas. An aggregate risk assessment is not needed for 1,3-PAD because the non-occupational exposures are limited to drinking water.
- Occupational handler exposures:
  - Occupational handler exposures include mop and sponge applications for surface sanitizing treatments and open pour applications for drain sanitizing treatments and MWF treatments. The dermal MOE of 2.9 for MWF treatment is of concern because it is less than the short and intermediate term LOC of 1,000. The dermal MOEs for surface and drain treatments are greater than the LOC and are not of concern. The inhalation MOEs are not of concern for any of the above scenarios because they are greater than the LOC of 1,000.
  - Machinists may be exposed when using treated MWFs. The inhalation MOE is not of concern because it is greater than the LOC of 1,000. The dermal MOE of 50 is of concern because it is less than the long-term LOC of 3,000.
  - Occupational post-application inhalation and dermal exposures are not anticipated for either surface sanitizing and drain treatments or the oil field flood water uses due to low vapor pressure, low application rate, and limited exposure potential.

### Ecological Risk Assessment Conclusions

- Risk to terrestrial species is not expected from the antimicrobial uses of 1,3-PAD based on limited exposure potential from the MWF uses.
- There are risks of concern for freshwater fish (acute), freshwater invertebrates (acute), aquatic vascular plants, and aquatic non-vascular plants from the MWF uses of 1,3-PAD

(degradation studies were not received during the drafting of the assessment. Therefore, these results are based on 0% degradation of 1,3-PAD).

- Chronic risks to fish and invertebrates could not be precluded and were assumed because chronic toxicity studies were not received during the drafting of the assessment.
- Assuming estuarine/marine water bodies have similar size and environmental conditions as freshwater, risks to estuarine/marine species are expected for uses in MWF applications.
- There were no reported ecological incidents for the registered antimicrobial uses of 1,3-PAD in the Agency's Incident Data System (IDS) as of March 12, 2021.
- New data (i.e., early life stage test with fathead minnow and aerobic degradation data) were submitted late in the DRA development process and were not fully reviewed or incorporated into the assessment. Although data may provide further clarification for the existing ecological risk conclusion, they are not expected to change the overall risk conclusions. These studies will be considered in future assessments.

#### **Communication**

- Minimal stakeholder feedback is anticipated.

## **Q1 AD/Antimicrobial Use DRA Summaries**

**None.**



## **Q1 BPPD/Biopesticide Use DRA Fact Sheets**

**None.**

## **Q1 BPPD/Biopesticide Use DRA Summaries**

**None.**

## **Q1 PRD/Conventional Use DRA Fact Sheets**

**None.**

## **Q1 PRD/Conventional Use DRA Summaries**

**None.**

# Q1 AD/Antimicrobial Use PID Fact Sheets

## Dimethoxane

### Background/Key Points

- Dimethoxane is a broad-spectrum microbiocide used for the preservation of materials to prevent degradation during manufacture, storage and service life.
- PID scheduled for December 2021 completion.
- There is one registered dimethoxane product with IFF Nutrition & Biosciences USA (formerly Dow Chemical Company)
- Dimethoxane is known to be a dermal sensitizer based on the acute tox study. IFF submitted the final study needed to quantify dermal sensitization this week, which was outstanding since 2019. AD completed the DRA in Sept 2020.
- AD proposes to move forward with closed loading requirements to address potential dermal sensitization risks to occupational handlers. Waiting for the data to be reviewed would likely delay this case until at least FY23 due to other program priorities.

### Use/Usage

- Dimethoxane is registered for use as a materials preservative in industrial adhesives, paints and coatings, emulsions, specialty industrial products, textiles, leather, and distillate fuels.
- There are no residential uses or direct/indirect food uses for the chemical.
- Application methods for dimethoxane include open pouring and closed metering systems. Dimethoxane-treated paints can be applied by a variety of methods, including by brush, roller, or airless sprayer.

### Human Health Risk Assessment Conclusions

- There are no direct or indirect food uses, therefore no dietary assessment was conducted.
- Drinking water exposure is not anticipated given half-life < 2 hours and unstable nature in water.
- Residential exposures were not assessed for the parent because dimethoxane is highly unstable in water.
  - Acetaldehyde is a degradate of dimethoxane and was assessed for residential handler inhalation exposures given use of the chemical as a paint preservative. The inhalation MOE is 760 and is not of concern because it is greater than the LOC of 30.
- Aggregate assessment not conducted given lack of food and drinking water exposures to aggregate with residential painter exposures.
- Occupational handler dermal MOE of 210 for systemic effects was calculated during open pouring but is above LOC of 100 and therefore not of concern.
- Dermal sensitization risks were not assessed because the studies were received just this week (data were due February 2019).
  - The Agency has acute data showing dimethoxane as a strong sensitizer but cannot quantify point of departure until studies are reviewed.

### Ecological Risk Assessment Conclusions

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- No expected risks to aquatic or terrestrial species (including pollinators).
- “No effect” ESA determination

### **Proposed Mitigation/Impacts**

- To address the potential for occupational handler risks of concern from dermal sensitization, the Agency is proposing to require closed loading of products containing dimethoxane for all materials preservative uses.
  - This mitigation is conservative because the Agency cannot currently quantify the degree to which dimethoxane is a dermal sensitizer due to resource constraints and other risk assessments to complete.
  - AD is proposing this risk mitigation measure to reduce the potential for exposure and risk to workers until the data can be reviewed.
- The sole registrant is aware of EPA’s proposal and shared potential concerns for smaller scale facilities where the cost of closed loading equipment may not be feasible. However, without the outstanding study or additional benefits information, the Agency determined this is the most appropriate route for mitigation.

### **Benefits**

- Due to the lack of available benefits information on dimethoxane (including a lack of information on any niche uses or unique properties of dimethoxane), the Agency cannot determine the magnitude of the benefits of using this chemical.
- In general, there are many alternative chemicals available for each of the registered industrial uses of dimethoxane.

### **Communications**

- AD met with the sole registrant for dimethoxane and discussed the planned mitigation. It is anticipated they will comment on the PID.

## Q1 AD/Antimicrobial Use PID Summaries

**Pelargonic acid, salts, and esters; fatty acid monoesters; capric acid; and caprylic acid**  
Release Combined Preliminary Work Plan and Proposed Interim Decision (2<sup>nd</sup> RR cycle). The pelargonic acid, salts, and esters; fatty acid monoesters; capric acid; and caprylic acid cases have been combined into one case given that each active ingredient possesses structural and chemical similarities and all are expected to have the same metabolic degradation pathway. Products containing these active ingredients are registered for antimicrobial, biochemical and conventional pesticide uses. The pelargonic acid, salts, and esters case is comprised of two active ingredients: ammonium nonanoate and pelargonic acid.

There are 39 registered products that contain pelargonic acid, salts, and esters as an active ingredient. Of the 39 registered products, 6 are registered as antimicrobial pesticides, 16 are registered as biochemical pesticides, and 17 are registered as conventional products. As an antimicrobial pesticide, products containing pelargonic acid, salts, and esters are used as cleaners/sanitizers on food processing and dairy equipment (hard non-porous food-contact surfaces). As a biochemical and convention pesticide, products containing pelargonic acid, salts, and esters are used as manufacturing-use products, desiccants, herbicides, algaecide regulators, plant growth regulators, insect repellents, insecticides, fungicides, and nematicides on or around food crops, non-food crops, and plants in agricultural, residential, or commercial areas.

There are 5 active EPA-registered products that contain fatty acid monoesters as an active ingredient. Of the 5 registered products, 2 are registered as antimicrobial pesticides and 3 are registered as biochemical pesticides. Antimicrobial products containing fatty acid monoesters as an active ingredient are registered for use as a preservative in industrial and institutional products; including oils, lubricants, solvents, non-potable/nonfood water systems, detergents, cleaners, and surfactants; and as a disinfectant/sanitizer for residential use on hard non-porous, non-food contact surfaces. Biochemical pesticide products containing fatty acid monoesters as an active ingredient are registered for use as manufacturing-use products to formulate into end-use products and as a miticide on food and non-food crops in indoor (i.e., greenhouse) and outdoor (i.e., field) agricultural areas.

There are 20 registered products containing capric (decanoic) acid as an active ingredient. Of the 20 products, 9 are antimicrobial pesticides and 11 are biochemical pesticide products. Antimicrobial products containing capric acid as an active ingredient are registered as food contact surface sanitizers in commercial food handling establishments, acid sanitizers for dairy and food processing equipment, tanks, vats, pails, pipelines, closed systems, clean-in-place systems, clean-out-of place systems, tanks and back-flush systems. Biochemical pesticide products containing capric acid as an active ingredient are registered for use as manufacturing-use products, fungicides, bactericides, herbicides, algaecides, insect repellents, insecticides, and nematicides on food crops, non-food crops, and on livestock in agricultural, residential, or commercial areas.

There are 22 registered products containing caprylic (octanoic) acid as an active ingredient. Of the 22 products, 10 are antimicrobial pesticides and 12 are biochemical pesticide products. Antimicrobial products containing caprylic acid as an active ingredient are registered for use as a food contact surface sanitizer in commercial food handling establishment, disinfectant in healthcare facilities. Biochemical pesticide products containing caprylic acid as an active ingredient are registered for use as manufacturing-use products, fungicides, bactericides,

herbicides, desiccants, algaecides, insect repellents, insecticides, and nematicides on food crops, non-food crops, and on livestock in agricultural, residential, or commercial areas.

There were no risks of concern identified for any of the active ingredients associated; therefore, no mitigation is being proposed.

*Anticipated stakeholder reaction:* minimal stakeholder reaction is anticipated.

# Q1 BPPD/Biopesticide Use PID Fact Sheets

None.

## Q1 BPPD/Biopesticide Use PID Summaries

### Laminarin

Release combined Preliminary Work Plan and Proposed Interim Decision (PWP-PID) for the second cycle of registration review. Laminarin is a common component of the human diet. Laminarin is typically extracted from brown algae. As a biochemical pesticide active ingredient, Laminarin stimulates the natural defense reactions of fruiting vegetables against gray mold, powdery mildew, downy mildew, fire blight, and bacterial spot. No new human health or ecological risks were identified. The Agency is making a "no effect" determination for endangered or listed species and their designated critical habitats. No mitigation or labeling changes are needed for the registration review of Laminarin. *Anticipated stakeholder reaction:* minimal stakeholder reaction is anticipated.

### Linalool

Release combined Preliminary Work Plan and Proposed Interim Decision (PWP-PID) for the second cycle of registration review. Linalool is a terpenoid alcohol found naturally in a variety of plants, flowers, and spices. Pesticide products containing Linalool as an active ingredient are registered for use outdoors and in semi-enclosed spaces as mosquito inhibitors and indoors for control of pests on pets and the spaces they inhabit in the form of a pet shampoo and residential carpet spray or powder. No human health or ecological risks were identified. The Agency is making a "no effect" determination for endangered or listed species and their designated critical habitats. No mitigation or labeling changes are needed for the registration review of Linalool. *Anticipated stakeholder reaction:* minimal stakeholder reaction is anticipated.

# Q1 PRD/Conventional Use PID Fact Sheets

## Diuron

### Current Status

- Joint conventional/antimicrobial registration review case.
- Diuron is a systemic phenylurea herbicide, algaecide, mildewcide, plant growth regulator, and antimicrobial preservative, first registered in 1967. The RED was completed in 2003. There are currently 88 Section 3 registrations and 28 Section 24(c) registrations.
- Diuron is used to control annual and perennial broadleaf and grassy weeds in a variety of agricultural crops, ornamentals, and non-agricultural sites, and as a cotton harvest aid.
- Important high percent crop treated (PCT) sites include asparagus, cotton (harvest aid and herbicide uses), orange, blueberry, aquaculture (algaecide in commercial fish farming), pears, hazelnuts, grapefruit and peaches, and rights-of-way. Regionally important sites include alfalfa, pineapple, and tree nuts.
- Diuron is also used as a mildewcide and materials preservative in paints, stains, coatings, adhesives, and sealants.
- The PID is now scheduled for release in Q2.

### Key Points

- The refined human health risk assessments identified potential cancer risks from food, drinking water, and residential handler painting exposures. Food and residential painting are each nearly of concern (right at cancer threshold) on their own while drinking water presents cancer risks of concern (exceeds cancer threshold) on its own.
- Given these cancer risks, there are aggregate cancer risks of concern, and the Agency cannot make an aggregate safety finding (food + drinking water + residential exposures).
- The Agency is proposing cancellation of nearly all conventional uses (including all food uses) to resolve cancer dietary risks of concern as well as application rate reductions and additional PPE requirements for paint uses to help mitigate ecological, residential, occupational and aggregate risks of concern.
- The team considered application rate reductions or use restrictions (*e.g.*, spot treatments) for conventional uses to resolve dietary risks but resulting use patterns would not be efficacious for users.
- Comments from conventional-use stakeholders did not provide any information that would enable DRA refinements sufficient to eliminate the risks of concern.
- Loss of diuron would have high impacts for pima cotton growers and fish aquaculture producers, while other conventional use sites analyzed have numerous alternatives available.
- There are also limited alternatives to diuron's use as an algaecide in preserved paints.

### Human Health Risk Assessment Conclusions

#### *Aggregate Risks*

- The most recent 2007 dietary assessment used PDP monitoring data for water and some fruit commodities, but diuron does not pass under current risk assessment guidelines and policies.
- Conventional Uses: total cancer dietary risk ( $2 \times 10^{-5}$ ) is driven by drinking water ( $2 \times 10^{-5}$ ) and food exposure ( $3 \times 10^{-6}$ ). Highest contributors to risk include drinking water (83%),



asparagus (5%), freshwater fish (2%), citrus (2%), cereal grains (2%), pears (1%), and livestock products (<1%).

- The food dietary assessment was partially refined using average percent crop treated (PCT) estimates and residue trial data for the highest contributing commodities. Further refinements are not expected to significantly improve risk estimates.
- The drinking water assessment is highly refined (all residues of concern and typical application rates). All use sites at typical rates present potential risks of concern. Additional characterizations explored would not resolve dietary risks.
- Antimicrobial uses: Residential handler cancer risk estimates from “Do It Yourself” (DIY) painting using preserved house paints:  $3 \times 10^{-6}$  for airless spray (used in aggregate) and  $2 \times 10^{-6}$  for brush/roller painting.
- **Aggregate cancer risks** (food + water + residential painting):  $2 \times 10^{-5}$

#### *Occupational Risks*

- Conventional Uses: occupational handler risks
  - Non-cancer (inhalation exposure): only one mixer/loader scenario of concern for dry flowable aerial broadcast applications to high-acreage field crops (MOE = 17, LOC = 30)
  - Cancer (dermal and inhalation exposure): up to  $3 \times 10^{-4}$  for private farm applicators and up to  $8 \times 10^{-4}$  for commercial applicators.
  - Occupational handler post-application cancer risks (dermal exposure only): up to  $3 \times 10^{-5}$  using 30-day average dose.
- Antimicrobial Uses: occupational handler cancer risks: up to  $8 \times 10^{-4}$  for airless spray painting,  $5 \times 10^{-4}$  for open pour liquids, and  $2 \times 10^{-4}$  for brush/roller painting.

### **Ecological Risk Assessment Conclusions**

#### *Conventional Uses*

- Potential acute and chronic risks of concern estimated for freshwater invertebrates, birds, and aquatic and terrestrial plants.
- Potential chronic risks of concern estimated for freshwater fish, mammals, and terrestrial invertebrates (pollinators).

#### *Antimicrobial Uses*

- Potential acute and chronic risks of concern to freshwater fish and invertebrates, and to vascular and nonvascular plants from exterior paint and coating uses.

### **Proposed Mitigation in PID**

#### *Conventional Uses*

- Propose cancellation of all food uses and nearly all agricultural use sites. Rate reductions necessary to resolve risks of concern from drinking water would not be efficacious for users.
- Propose cancellation of non-agricultural use sites (e.g., rights-of-way, utilities, roadways); reduced application rates would not be efficacious while spot treatments would not be preferred by users.
- Cancellation of these conventional use sites would also mitigate ecological risks of concern.
- Team is exploring whether a couple minor use sites could be retained, such as:
  - Cotton defoliant/harvest aid use (current rate of 0.026 lbs a.i./A is 1/30<sup>th</sup> of average herbicide rate).
  - Residential aquariums/containerized ponds (applying tablets).

- BEAD benefits assessment concludes that, in general, impacts of potential cancellation will be low for most use sites (e.g., herbicidal use in asparagus, blueberries, citrus, cotton, pineapple; and as a defoliant use in upland cotton) since several alternatives are available that provide effective control of diuron target pests.
  - However, in pima cotton defoliation and aquaculture production, growers have limited alternatives, and the loss of diuron would greatly impact their ability to control weed pests.

### *Antimicrobial Uses*

- Rate reductions are needed to mitigate cancer risk from DIY residential painting and occupational painting. Registrants have proposed a 50% reduction from 6000 ppm to 3000 ppm.
  - Residential risks are further reduced with rate reduction:
    - With the 50% rate reduction, estimates from “Do It Yourself” (DIY) painting go from  $3 \times 10^{-6}$  to  $1.4 \times 10^{-6}$  for airless spraying. For brush roller, risk estimates go from  $2 \times 10^{-6}$  to  $8.7 \times 10^{-7}$
  - Occupational painter brush/roller risks can be eliminated with rate reductions alone
    - For occupational painters using a brush/roller, cancer risks of concern go from  $2 \times 10^{-4}$  to  $7.6 \times 10^{-5}$
  - Occupational painter airless sprayer risks cannot be eliminated with rate reductions alone
- PPE is necessary to eliminate risks for professionals using an airless sprayer: a respirator, painter’s hat, cotton coveralls, chemical resistant gloves
- For occupational painters using airless sprayers, cancer risk goes from  $8 \times 10^{-4}$  to  $1.91 \times 10^{-5}$  with the additional PPE and rate reduction. Registrants have also proposed paint can labeling that would indicate the product is only intended for outdoor use. However, we do not have data to quantitatively assess outdoor only use.
  - There are limited options to address risk from exposure to treated articles like paints as these labels have previously not been regulated under FIFRA if the treated article exemption applies. Requiring language on these labels would be novel. Requiring PPE would be similar to PMRA’s approach.
- Many professional painters are independent contractors and may be unlikely to get fit tested or adopt PPE requirements.
  - PMRA plans to address these concerns through a stewardship program. The AD team is currently considering the feasibility of a stewardship program.
  - PPE is the only option to make a safety finding for many paint preservatives.
- Benefits and Alternatives: The use of an algacide in antimicrobial paints and coatings is considered a niche use and there are a limited number of currently registered algacides for exterior antimicrobial control of algae
  - Alternatives include OIT and terbutryn.
    - OIT has limitations for algal control in paints and coatings and is considered primarily, by the market, as an in-can bactericide with limited algal efficacy.
  - Formulations containing terbutryn are extremely prone to instability due to chemical incompatibility of terbutryn with other active ingredients such as IPBC.

### **Communications**

- PRD met with conventional registrants to discuss mitigation and they were not anticipating the proposed cancellations.

- Due to proposed cancellation of most use sites, EPA is expecting significant additional feedback from stakeholders (particularly for conventional uses).
- PRD will release an OPP update (listserv) to notify public of PID publication and start of public comment period.
- Outreach planned with USDA to inform them about proposed conventional use cancellations.
- AD has been working the American Coatings Association (ACA) and the diuron registrants to come up with feasible rate reductions and mitigation proposals
- AD continues to coordinate with PMRA on a North American strategy for paint preservatives mitigation.
- If AD moves forward with PPE requirements for painters, additional communications to painters trade associations may be needed
- OPP Update needed to inform the public of novel PPE requirements for painters

## Dithiocarbamates (Thiram, Ferbam, Ziram) PID

○ (Briefed Ed on August 31<sup>st</sup>, 2021)

Chemical Name	Registered Uses
<b>Thiram</b>	<ul style="list-style-type: none"> <li>• <b>Agricultural use sites:</b> foliar spray on peaches and strawberries</li> <li>• Seed treatment for a variety of crops such as soybeans, peanuts, and sugar beets and small-seeded or dry-seeded vegetables</li> <li>• <b>Non-agricultural use sites:</b> coniferous/evergreen/softwood trees, flowering and non-flowering plants, grass/turf, shrubs/bushes/vines, trees, as well as a commercial dip treatment for ornamental seeds or bulbs.</li> <li>• Animal repellent on ornamentals, shrubs/bushes/vines, and trees</li> </ul>
<b>Ferbam</b>	<ul style="list-style-type: none"> <li>• <b>Agricultural use sites:</b> apples, citrus, cranberries, mangoes (in Florida), pears, peaches, and nectarines.</li> <li>• There are no non-agricultural use sites and no residential uses.</li> </ul>
<b>Ziram</b>	<ul style="list-style-type: none"> <li>• <b>Conventional agricultural use sites:</b> almond, apple, apricot, blueberry, cherry, grape, hazelnut, nectarine, peach, pear, pecan, tomato, Christmas tree plantation, conifer, ornamentals.</li> <li>• <b>Non-agricultural antimicrobial use sites:</b> materials preservatives for adhesives, wallboard joint compounds, paints, paper and paperboard, paper coatings, caulks and sealants.</li> </ul>

Chemical Name	Risk Summary
<b>Thiram</b>	<p><b>Human health:</b></p> <ul style="list-style-type: none"> <li>• Dermal and inhalation risks of concern from foliar uses were identified for occupational handlers with current label-required PPE (dermal MOEs range from &lt;1 to 590 with LOC = 100; inhalation MOEs range from &lt;1 to 2,500 with LOC =30). Several scenarios are still of concern for dermal and inhalation with additional PPE and/or engineering controls.</li> <li>• Seed treatment: dermal and inhalation risks of concern identified for occupational handlers with current label-required PPE with some remaining inhalation risks with additional PPE (PF10 respirator and double layer clothing + gloves) while most of the dermal risks of concern remain.</li> <li>• Occupational post-application risks of concern were identified at 24 hours, the current restricted entry interval. Some scenarios are still of concern at more than 30 days after treatment.</li> </ul> <p><b>Ecological:</b> Potential risks to mammals, birds, fish and aquatic invertebrates, and terrestrial invertebrates based primarily on foliar registered uses.</p> <p>The seed treatment uses are a risk of concern for small birds and small mammals, especially.</p>

<b>Ferbam</b>	<p><b>Human health:</b></p> <ul style="list-style-type: none"> <li>• For occupational handlers, dermal risks are not of concern at currently labeled PPE or with additional PPE/engineering controls.</li> <li>• All occupational handler inhalation risks are of concern even with the highest level of PPE, except two groundboom and mechanically pressurized handgun scenarios (for peaches and cranberry). <ul style="list-style-type: none"> <li>○ Inhalation MOEs for the scenarios still of concern (with highest PPE) range from 0.052 to 20 [LOC=30].</li> </ul> </li> <li>• Occupational post-application risks of concern were identified at 24 hours, the current restricted entry interval. MOEs of concern range from 3.7-77 [LOC=100]. Some scenarios are still of concern at more than 30 days after treatment.</li> </ul> <p><b>Ecological:</b> Potential risks to mammals, birds, fish and aquatic invertebrates, and terrestrial invertebrates.</p>
<b>Ziram</b>	<p><b>Human health:</b></p> <p><i>Conventional</i></p> <ul style="list-style-type: none"> <li>• All occupational handler uses result in risk estimates of concern, by either, and in some cases both, the dermal and inhalation route, with the highest level of PPE and/or engineering controls.</li> <li>• Dermal risk estimates for all scenarios result in MOEs ranging from 4.7 to 6,400, approximately half of which are of concern (i.e., &lt; LOC of 100) assuming label-specified clothing and PPE. All scenarios, except for one can be mitigated with additional PPE or EC.</li> <li>• Inhalation risk estimates are MOEs ranging from 0.015 to 54, all of which are of concern (i.e., &lt; LOC of 30) assuming label specified PPE (a PF10 respirator), with the exception of one risk estimate.</li> <li>• Occupational post-application risks of concern were identified at 48 hours, the current restricted entry interval. MOEs of concern range from 2.3-630 [LOC=100]. Some scenarios are still of concern at more than 30 days after treatment.</li> </ul> <p><i>Antimicrobial</i></p> <ul style="list-style-type: none"> <li>• Residential handler risks of concern were identified for inhalation (MOE 0.024 airless sprayer; MOE 23 brush/roller; LOC=30) and dermal (MOE 10 airless sprayer; MOE 57 brush/roller; LOC=100) exposures resulting from painting using ziram preserved paints.</li> <li>• Occupational handler risks of concern were identified for inhalation (MOE 0.0071 airless sprayer; MOE 9.1 brush/roller; LOC=30) and dermal (MOE 7.5 airless sprayer; MOE 36 brush/roller; LOC=100) exposures resulting from painting using ziram preserved paints and the open pour of ziram powder formulations (inhalation MOE 0.0079; LOC=30), (Dermal MOE 36; LOC=100).</li> </ul> <p><b>Ecological:</b> Potential risks to mammals, birds, fish and aquatic invertebrates, and terrestrial invertebrates from conventional uses.</p>

	For antimicrobial uses, risks to freshwater fish are assumed from the paint use. Due to the sensitivity of freshwater fish to chronic exposures to ziram and thiram's (thiram is the major degradate of ziram) potential for persistence in the environment for days to weeks, one painted house immediately adjacent to a waterbody could result in risk to freshwater fish.
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<b>Chemical Name</b>	<b>Proposed Mitigation</b>
<b>Thiram</b>	<ul style="list-style-type: none"> <li>• Cancellation of all uses except for animal repellency and seed treatment</li> <li>• Requiring PPE (DL/G and/or PF10) for seed treatment uses</li> <li>• Update surface water advisory language, environmental hazard statements, and runoff prevention statements.</li> </ul>
<b>Ferbam</b>	<ul style="list-style-type: none"> <li>• Cancellation of all uses except for cranberry and peach</li> <li>• Requiring PPE (SL/G and PF50) for both cranberry and peach</li> <li>• REI of 22 days for cranberry</li> <li>• Update surface water advisory language, environmental hazard statements, and runoff prevention statements. Add pollinator statements.</li> </ul>
<b>Ziram</b>	<ul style="list-style-type: none"> <li>• Cancellation of all conventional uses and the antimicrobial paint use</li> <li>• Application rate reduction of all other uses (adhesives, caulks, sealants, etc.) to 1,680 ppm</li> <li>• Closed loading or water-soluble packet formulation for mixing.</li> </ul>

## Iprodione

### Current Status

- Iprodione is a systemic fungicide which is registered for use on a variety of crops, sod, turfgrass, ornamentals, and for commercial seed treatment uses.
- PID scheduled for December 2021.

### Key Points

- There are 3 residues of concern: parent and degradates RP30228 and 3,5-dichloroaniline (3,5-DCA). The parent and RP30228 were assessed separately from 3,5-DCA.
- **3,5-DCA** cancer dietary assessment resulted in a cancer risk estimate of  $2 \times 10^{-5}$  with surface water occupying 96% of the total exposure.
- **Iprodione** cancer dietary assessment resulted in a cancer risk  $1 \times 10^{-4}$  with ground water occupying 97% of the total exposure.
- The Agency has explored a number of refinements and alternate scenarios based primarily on dietary and aggregate risk concerns and regional analyses to develop a mitigation plan that preserves essential benefits.

### Human Health Risk Assessment Conclusions

- Human health DRA identified potential risks for:
  - Dietary (worst case—cancer risk in  $10^{-4}$  range)
  - EDWCs modeled using new PWC scenarios and Formation-Degradation Modeling
    - Refined using use pattern-specific PCA, average application rates, Golf Course Adjustment Factors, and consideration of the effect of soil pH on persistence and the number acres grown in different states.
  - Residential post-app (lowest MOE = 42 vs LOC of 100; cancer risks in  $10^{-4}$  range)
  - Aggregate risk
  - Occupational handler (several scenarios with MOEs < 100)
  - Occupational post-application (potential risks of concern even with extended REIs)

### Ecological Risk Assessment Conclusions

- Used formation-degradation modeling for surface water RQ calculations, and comparison to mean Kenaga and LOAEC values for terrestrial RQ calculations
- Ecological DRA identified potential risks to:
  - Fish, aquatic invertebrates, aquatic plants
  - Birds, mammals, pollinators

### Benefits

- Primary uses in turfgrass, stone fruit, almonds, carrots, and onions
- Broad-spectrum control of various fungal diseases
- Several alternatives available
- Iprodione is the only registered fungicide in the FRAC group 2

### Proposed Mitigation, Impacts

- Explored a number of alternate risk management scenarios to develop proposal.

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- Mitigation Proposal:
  - Limit turf use to golf course tees and greens only, with one application/year at 2.6 lb ai/A.
  - No residential turf.
  - Only allow one application/yr for *all* uses.
  - Eliminate use on lower benefit uses sites: peanuts, beans/peas, blueberries, caneberries.
  - Limit ornamentals use to greenhouses only.
  - Additional PPE (mainly double layer clothing) for select uses.
  - Prohibit use of mechanically pressurized handguns for some uses.
  - Mandatory drift management labeling.
  - Rate reductions are needed for turf and grapes.
- Risk estimates based on risk management plan:
  - Aggregate risk (residential and food-only dietary)—no concerns for non-cancer; dietary risks  $1.3 \times 10^{-6}$  (DWLOC = 1.89 ppb)
  - Occupational handlers—no concerns with added PPE
  - Mitigates human health/ecological risk concerns, except cancer occupational post-application risks, which will be addressed after comments on use deletions, in particular, are evaluated.
- ✦ Impacts of mitigation work being finalized; proposed risk mitigation based on detailed evaluation.

### **Communications**

- PRD met with registrants to discuss mitigation. They are aware of the updated risk picture and proposed use cancellations.



# **Q1 PRD/Conventional Use PID Summaries**

**None.**

# Q1 AD/Antimicrobial Use ID Fact Sheets

## Pentachlorophenol

### Background/Key Points

- Pentachlorophenol is a restricted use pesticide (RUP) formulated as a heavy-duty chemical wood preservative used in the pressure or thermal treatment of lumber, timber, posts, poles, and other wood members intended for exterior use.
- There are four registered antimicrobial products containing pentachlorophenol (PC Code 063001) as an active ingredient: one technical/formulation intermediate and three end-use products.
- In response to the 2008 RED, industry installed engineering controls at treatment facilities to reduce worker risks as part of its mitigation efforts. It also conducted a new worker exposure study that showed these mitigations lowered exposures to workers; however, the DRA indicated that risks still remain for occupational handlers of pentachlorophenol even with updated engineering controls.
- There are human health risks of concern for occupational handlers for long-term inhalation and dermal exposures.
- Cancer risk is  $1 \times 10^{-3}$
- There are no occupational post-application, residential, dietary, or drinking water exposures due to restrictions on the uses of pentachlorophenol and therefore no risks of concern.
- There are no ecological risks of concern

### Mitigation Proposed in the PID

The PID proposed cancellation of all registrations of pentachlorophenol due to the following rationale:

- The risks in the DRA outweigh the benefits of this chemical given the emergence of viable, safer alternatives such as copper naphthenate and DCOIT, along with well-established wood preservatives such as chromated arsenicals and creosote, which would provide stability in the utility pole market.
- The sole manufacturer, KMG-Bernuth, is ceasing production of the chemical in 2021 and no company has indicated plans to manufacture pentachlorophenol.
- In 2012, signatories of the Stockholm Convention (94 countries) banned pentachlorophenol. In July 2020, PMRA announced a proposal to cancel pentachlorophenol.

The proposed cancellation will be enacted on the following timeline:

- Registrants must voluntarily cancel their registrations by 2 years from publication of the ID
- Use of existing stocks will be allowed for 3 years following the cancellation of product registrations

### Changes between PID and ID

- None

**Communications**

- AD will work with OPS to develop a communications strategy for the cancellation beyond the normal public notice. AD has been actively communicating with registrants throughout the risk assessment and mitigation development process. AD anticipates that environmental groups and non-governmental organizations will support the decision to cancel pentachlorophenol while registrants and treaters of pentachlorophenol will express the need to utilize the full five-year phase-out period to transfer to alternative wood preservatives.

## Chromated Arsenicals and Dichromic Acid

### Background/Key Points

- Chromated arsenicals and dichromic acid are formulated into various heavy-duty chemical wood preservatives that are Restricted Use Pesticides (RUP), used solely for commercial pressure treatment of posts, utility poles and pilings.
- In response to the 2008 Reregistration Eligibility Decision (RED), by 2013 industry had installed engineering controls at treatment facilities to reduce worker risks as part of its mitigation efforts. The effect of the RED engineering controls was measured in a worker exposure study.
- In the DRA published in 2019, based on the results of the new worker exposure study, EPA concluded that the RED mitigation measures lowered exposures to workers; however, risks of concern remain even with updated engineering controls.
- Human Health Risk Assessment Conclusions:
  - There are no dietary or residential exposures for creosote based on the registered use patterns.
  - There are no occupational post-application, residential, dietary, or drinking water exposures due to restrictions on the uses of creosote and therefore no risks of concern.
  - There are human health risks of concern for occupational handlers for dermal and inhalation exposures to arsenic and chromium.
    - Arsenic: Long-term non-cancer risks of concern for dermal and inhalation exposures. Cancer risk for arsenic ranges from  $1.8 \times 10^{-3}$  to  $6.4 \times 10^{-4}$  for dermal exposures and ranges from  $1.7 \times 10^{-3}$  to  $1.7 \times 10^{-4}$  for inhalation exposures
    - Chromium: Short- intermediate-, and long-term inhalation exposures. Inhalation cancer risks range from  $1 \times 10^{-3}$  to  $5 \times 10^{-4}$
- Ecological Risk Assessment Conclusions:
  - There are ecological risks of concern for:
    - Chronic risk to listed and nonlisted aquatic invertebrates is expected from exposure to arsenic and chromic acids.
    - Arsenic acid also poses risk to listed and nonlisted aquatic plants.
  - Exposure and risks to terrestrial organisms are not expected.

### Mitigation Proposed in the PID

EPA and the American Chemistry Council's (ACC) Arsenicals Wood Preservative Task Force (AWPTF) have agreed to include several mitigation measures in the PID to decrease occupational handler exposures, including:

- Requiring additional respiratory and dermal PPE, including respiratory protection and chemical resistant gloves;
- Requiring cylinder door exhaust fans to run while the cylinder door is open;
- Ongoing training of occupational handlers required on labels; and
- Labeling changes in line with those proposed for other wood preservatives (clarifying use sites and rates, specific references to third party standards).

### **Changes between PID and ID**

- Changes to the required respirator language to be included in the product labels to reflect current respirator requirements.
- Removal of quality control sampling from certain personal protective equipment requirements because quality control sampling is conducted at ambient temperature and pressure.
- Removal of training requirements for occupational handlers that were proposed in the PID after discussions with PRD's CWPB which recommended that AD coordinate with states to ensure Certified Applicator trainings are sufficiently protective of heavy-duty wood preservatives through recertification programs for RUPs.
- Changes to the list of required use sites listed on the product labels to reflect wood used in above ground, ground contact, or marine settings.
- Changes to the ventilation options available to treaters post-treatment to provide equivalent worker protection while allowing flexibility based on variability in treatment facility equipment and layouts.
- Clarification that the residential uses of wood treated with chromated arsenicals and dichromic acid were withdrawn by the registrants rather than cancelled by the Agency in 2003.

### **Communications**

- No rollout is proposed beyond the normal public notice. OPP has been actively communicating with registrants throughout the risk assessment and mitigation development process. AD anticipates support for the required mitigation measures from the registrants.

## Creosote

### Background/Key Points

- Creosote is a restricted use pesticide (RUP) formulated as a heavy-duty chemical wood preservative used in the pressure or thermal treatment of utility poles/cross-ties, railroad ties, bridge timbers, fence and guardrail posts, foundation timbers, marine and foundation round piles, sawn lumber and timber products, and exterior structural composite glue laminated wood and plywood products.
- Treated wood is intended for exterior/outdoor use in posts, poles, and other wood members intended for exterior use.
- There are 15 registered antimicrobial products containing creosote (PC Code 025004) as an active ingredient: 13 end-use products and 2 technical intermediates.
- In response the 2008 RED, industry installed engineering controls at treatment facilities to reduce worker risks as part of its mitigation efforts. It also conducted a new worker exposure study that showed these mitigations lowered exposures to workers; however, the DRA indicated that risks of concern remain for occupational handlers of creosote even with updated engineering controls.
- Human Health Risk Assessment Conclusions
  - There are no dietary or residential exposures for creosote based on the registered use patterns.
  - There are human health risks of concern for occupational handlers for long-term dermal exposures and for short-, intermediate-, and long-term inhalation exposures.
  - Cancer risk is  $1 \times 10^{-4}$
  - There are no occupational post-application, residential, dietary, or drinking water exposures due to restrictions on the uses of creosote and therefore no risks of concern.
- Ecological Risk Assessment Conclusions
  - Risk to birds, terrestrial mammals, and terrestrial plants is likely minimal due to lack of exposure.
  - Potential risks to fish and invertebrates from the use of creosote-treated wood in aquatic and railroad structures.

### Mitigation Proposed in the PID

The PID proposed a number of mitigation measures to decrease occupational handler exposures, including:

- Requiring additional respiratory and dermal PPE, including respiratory protection, chemical resistant coveralls, and chemical resistant gloves;
- Requiring air filtration or fresh air ventilation into control room;
- Application restrictions following treatment;
- Ongoing training of occupational handlers required on labels;
- Requiring cylinder door exhaust fans to run while door is open;
- Updating best management practices for wood installed in sensitive and aquatic environments; and
- Labeling changes in line with those proposed for other wood preservatives (clarifying use sites and rates, specific references to third party standards).

**Changes between PID and ID**

- Minor changes were made to the required personal protective equipment (PPE) to distinguish the PPE requirements between external and internal repairs to the treatment chambers.
- Removal of training requirements for occupational handlers that were proposed in the PID after discussions with PRD's CWPB which recommended that AD coordinate with states to ensure Certified Applicator trainings are sufficiently protective of heavy-duty wood preservatives through recertification programs for RUPs.

**Communications**

- No rollout is proposed beyond the normal public notice. OPP has been actively communicating with registrants throughout the risk assessment and mitigation development process. AD anticipates support for the required mitigation measures from the registrants.

**Q1 AD/Antimicrobial Use ID Summaries**

**None.**

# Q1 BPPD/Biopesticide Use ID Fact Sheets

None.

## Q1 BPPD/Biopesticide Use ID Summaries

### Cinnamaldehyde

Release Interim Decision. Cinnamaldehyde is registered for use as a fungicide, insecticide, algacide and miticide for agricultural crops, horticultural crops, and turf. Pesticide products containing cinnamaldehyde as an active ingredient are registered for use to control a variety of pests including aphids, mites, leafhoppers, whiteflies (including silverleaf and greenhouse), thrips (including western flower), algae, moss, and liverworts/hornworts/pearlworts. Fungicidal cinnamaldehyde products are registered for use to control powdery mildew, rhizoctonia, pythium, dollar spot, and pitch canker disease. It is also registered as a microbicide for use in controlling bacteria in oil field processing, gas production, gas storage fields, water holding tanks, and fuel storage tanks. No human health or ecological risks were identified. The Agency is making a "no effect" determination for endangered or listed species and their designated critical habitats. No mitigation or labeling changes are needed for the registration review of cinnamaldehyde.

*Anticipated stakeholder reaction:* minimal stakeholder reaction is anticipated.

### Farnesol and Nerolidol

Release Interim Decision for the second cycle of registration review. Farnesol and nerolidol are naturally occurring sesquiterpene mite attractants that were originally isolated from essential oils found in plants such as rose, citronella, and lemongrass. These attractants are best described as parahormones, being most recently isolated from female mites. Pesticide products containing farnesol and nerolidol are registered for use in the control of mites on agricultural crops and ornamentals. The Agency is making a "no effect" determination for endangered or listed species and their designated critical habitats. No mitigation or labeling changes are needed for the registration review of the active ingredients in this case. *Anticipated stakeholder reaction:* minimal stakeholder reaction is anticipated.

### *Nosema locustae*

Release Interim Decision for the second cycle of registration review. *Nosema locustae* is a naturally occurring microorganism that infects the fat bodies of grasshoppers after consumption of the bait. It is registered for use to reduce or control various grasshoppers and Mormon crickets. Pesticide products containing *Nosema locustae* are registered for use in residential and agricultural settings. No human health or ecological risks were identified. The Agency is making a "no effect" determination for endangered or listed species and their designated critical habitats. *Anticipated stakeholder reaction:* minimal stakeholder reaction is anticipated.

### *Ulocladium oudemansii* (U3 Strain)

Release Interim Decision for the second cycle of registration review. *Ulocladium oudemansii* (U3 Strain) is a naturally occurring soil fungus existing as a saprophyte of dead and decaying plant matter. As a pesticide it is used to protect fruit crops, vegetable crops and ornamental plants from certain plant pathogenic diseases by competing for the same ecological niches and nutrients. Pesticide products containing *Ulocladium oudemansii* (U3 Strain) are registered for agricultural use such as in outdoors, greenhouses, horticultural crops (food commodities), and ornamental



plants (greenhouses and nurseries). No human health or ecological risks were identified. The Agency is making a "no effect" determination for endangered or listed species and their designated critical habitats. No mitigation or labeling changes are needed for the registration review of *Ulocladium oudemansii* (U3 Strain). *Anticipated stakeholder reaction*: minimal stakeholder reaction is anticipated.

## Q1 PRD/Conventional Use IDs and Case Closure Fact Sheets

None.

## Q1 PRD/Conventional Use IDs and Case Closure Summaries

### Amitraz

Release Interim Decision. Amitraz is an insecticide and miticide. It is used in dog collars to provide protection from tick species of public health concern and is used by beekeepers as a highly effective miticide to control varroa mites. There are no human health or ecological risks of concern. Colony level risks to honeybees were identified for only within the treated colony for registered varroa mite control uses. A “No Effect” determination for all federally listed species and a “No Modification” determination for designated critical habitats have been made based on limited exposure potential to non-target organisms outside of beehives. To determine whether the dog collar use meets the FIFRA registration standard, EPA is considering requiring enhanced incident reporting and sales data as a separate action (outside of the ID) that will help the Agency determine whether any changes to the dog collar registration and label are necessary. No mitigation or label changes are being required in the amitraz interim decision (ID). *Anticipated stakeholder reaction* is minimal.

### Difenoconazole

Release Interim Decision. Difenoconazole is a systemic broad-spectrum triazole fungicide registered for use as seed treatment on a number of cereal grain crops, cotton, canola, and potato seed pieces; as a foliar application to rice, fruits and nuts, vegetables, and field crops; and for post-harvest applications on some fruits and vegetables. Products containing difenoconazole are also registered for use on golf course turf and ornamental plants in commercial and residential landscaped areas. Difenoconazole is a demethylation inhibitor fungicide which acts by preventing development of fungal cell membranes in target pathogens giving it protective, curative, and eradication properties against plant diseases. There are no human health risks of concern. There are potential ecological risks of concern for fish, aquatic invertebrates, birds, and mammals. Risks are considered low for honeybees and aquatic plants. Risk mitigation includes a requirement that treated seeds be soil-incorporated to limit exposure to birds and mammals. Label clarifications include restrictions for foliar rice uses in flooded fields, clarification of maximum annual application rates, advisory spray drift measures, surface and ground water advisories, a nontarget organism advisory, fungicide resistance management language, and updated glove language. Little to no impacts are expected from the risk mitigation. Anticipated stakeholder reaction is minimal.

### Fenbuconazole

Release Interim Decision. Fenbuconazole is a triazole (conazole) fungicide currently registered for use on a variety of food and feed crops including cherry, orange, blueberries, almond, grapefruit, and apple. Fenbuconazole may be applied via ground and aerial equipment on all crops. In addition, it can be applied via chemigation on cranberries. Fenbuconazole has no registered residential or non-agricultural (including antimicrobial) uses. There are no human health risks of concern. There are potential ecological risks of concern for mammals (chronic), estuarine/marine fish (chronic, for cranberry use only), and terrestrial invertebrates (chronic for larval and adult). No mitigation is being proposed. Label clarifications include an update to the glove label statement, fungicide resistance management language, and the addition of advisory spray drift management

language across all product labels. Little to no impacts to the current use patterns of fenbuconazole are expected from the proposed label updates. Anticipated stakeholder reaction is minimal.

### Isoxaflutole

Release Interim Decision. Isoxaflutole is a preplant, preemergence, or postemergence HPPD inhibiting herbicide primarily used to control broadleaf weeds. Isoxaflutole is only registered for agricultural use and use sites include field corn, seed corn, corn grown for silage, and for isoxaflutole-resistant soybean. Use of isoxaflutole is only permitted in 33 states and each label specifies the subset of states where use is permitted. It is applied via ground boom or incorporated into soil above the seed planting zone and all labels are restricted use. Dietary cancer risks were identified ( $3 \times 10^{-6}$ ) and >80% of the risk was derived from drinking water exposure. However, dietary cancer risks assumed the estimated drinking water exposure from the Florida Central Ridge groundwater scenario and isoxaflutole is not permitted for use in Florida. Dietary cancer risks were reassessed using the Wisconsin Central Sands scenario and risks were  $1 \times 10^{-6}$ . Ecological risks of concern were identified for terrestrial plants. The majority of isoxaflutole incidents involved damage to plants, and many of these incidents have occurred from direct application to corn (the target crop). Label clarifications include mandatory spray drift language, updated herbicide resistance management statements, and updated gloves statements on all product labels. Little to no impacts are expected from the mitigation. *Anticipated stakeholder reaction* is minimal.

### Mesotrione

Release Interim Decision. Mesotrione is a member of a group of systemic triketone compounds that inhibit the enzyme *p*-hydroxyphenyl pyruvate dioxygenase (HPPD). Mesotrione is registered for use as a pre-plant and post-emergence herbicide to control broadleaf weeds in agricultural and non-agricultural areas. Registered agricultural use sites for mesotrione include blueberries, caneberries, cranberries, rhubarb, popcorn, field corn, grass grown for seed, sod, sweet corn, okra, asparagus, millet, oats, sorghum, sugarcane, flax, and soybeans. Registered non-agricultural use sites for mesotrione include athletic fields, recreational areas, residential lawns, and golf courses. Mesotrione is applied via ground and aerial application equipment. There are no human health risks of concern identified. There are potential ecological risks of concern identified for mammals, terrestrial plants, and aquatic plants. Risk mitigation includes mandatory spray drift measures, surface water and ground water advisories, a nontarget organism advisory, herbicide resistance management language, and updated glove language. Most usage is on corn; it plays an important role in managing glyphosate resistant weeds and slowing the development of glyphosate resistance. Little to no impacts are expected from the risk mitigation. Anticipated stakeholder reaction is minimal.

### Metaldehyde

Release Interim Decision. Metaldehyde is a systemic molluscicide used to control slugs and snails. Metaldehyde is registered for a variety of residential and agricultural use sites including (but not limited to) citrus, berries, leafy vegetables, grasses grown for seed, watercress, and soybean. Metaldehyde may also be used for state and federal mollusk eradication initiatives where application is permitted for wide area/general outdoor treatment. Metaldehyde is only applied via ground application and is formulated as pelleted granules or as a liquid. There is one aerial use of a pelleted formulation (Oregon SLN-OR110016) for Christmas tree plantations. The majority of metaldehyde applications are soil directed and foliar directed applications are only permitted for grass grown for seed, watercress, Christmas trees (in spring with SLN only) and the state and

federal mollusk eradication uses. There were no human health risks of concern identified. There are potential risks of concern for birds, mammals and domestic dogs. Risks to pollinators are unclear and a full suite of Tier I data is not available. Significant mitigation was implemented with the 2006 RED (amended in 2007) to reduce domestic dog incidents associated with residential products. While incidents have declined since the implementation of the RED mitigation, over 40 domestic dog incidents occurred between 2017 and 2019 and 18 of these incidents involved mortality. However, the end use product associated with the majority of incidents is no longer marketed/ produced by the registrant. Label clarifications include updated personal protective equipment language, advisory resistance management language, and plant back intervals. Little to no impacts are expected from the mitigation. Anticipated stakeholder reaction is minimal.

### Oxyfluorfen

Release Interim Decision. Oxyfluorfen is an herbicide first registered in 1979 and currently registered for use on ornamentals, some residential sites, and on a wide variety of crops including forestry, corn, soybeans, grapes, coffee, and bananas. There are 4 technical registrants, 17 end-use registrants and 37 Section 3 registrations and 8 SLN registrations. Identified risks of concern include dietary and residential cancer risks, cancer and non-cancer risks of concern to occupational handlers for several different uses and application methods, post-application risk to agricultural workers hand-setting irrigation pipe in orchards, and to most assessed classes of wildlife. Proposed mitigation for aggregate (dietary and residential cancer) risks includes cancelling residential use, cancelling use on bananas, requiring applications to orchards and vineyards be made in bands no more than 30% of the total area of the orchard, decreasing the number and/or rate of application for 9 crops, extending a vegetated filter strip to all labels, requiring mandatory spray drift language on all agricultural use label with a coarse or coarser spray required. To mitigate non-cancer risks to occupational handlers from backpack applications, the Agency has proposed to: require all backpack sprays be directed at the ground; remove application by backpack sprayer for landscape tree, shrubs, and bushes; remove application by mechanically pressurized handguns; remove hand application of granules for all uses; reduce the allowed maximum concentration of the applied solution for certain crops; require additional PPE for certain uses; remove the application of oxyfluorfen by chemigation to orchards and vineyards. The Agency also proposed adding runoff advisory language, non-target organism protection advisory language and herbicide resistance language to all labels.

### Rotenone

Release Interim Decision. Rotenone is a Restricted Use piscicide used to kill undesirable and/or invasive fish for fisheries management and habitat conservation and restoration. There are currently two registrants with 8 products. All current active products require adherence to an extensive SOP which is considered collateral labeling, describing how to use the product. There is currently no registered alternative to rotenone for use as a general piscicide since the voluntary cancellation of antimycin-A in 2017. The Agency identified potential risks to mixers, loaders, and applicators. Risk mitigation measures include requiring adherence to the SOP on all labels, requiring a certified applicator to be on site, requiring improved placarding on all labels, restricting swimming and recreational use after treatment on all labels, and harmonizing all labels to use the same quantitative, detailed drinking water protection instructions. The Agency also identified acute risks of concern for aquatic animals. Risk mitigation measures include requiring a coarse droplet size, spray drift mitigation and application site restrictions for aerial application and restricting application in marine/estuarine environments. *Stakeholder Reaction:* EPA received 29 public

comments on the PID from state and federal agencies, including USDA and USFWS, indicating that the proposed cancellation of aerial application and the cold-temperature application restrictions would substantially impact agencies' ability to control invasive fish species and preserve native biodiversity in freshwater aquatic habitats. The Agency modified the previous mitigation proposed in the PID to address these concerns.

### Sodium Cyanide

Release Interim Decision Amendment. The Interim Decision for sodium cyanide was published in August 2019, followed by a Revised ID in January 2020. The Interim Decision Amendment is being issued to update endangered species label language after completing the Endangered Species Act consultation with Fish & Wildlife Services (FWS). Sodium cyanide is a predicide and an insecticide; all products are restricted use pesticides. As a predicide, sodium cyanide is manufactured as an encapsulated single-dose product, which is inserted into an M-44 spring loaded ejector device to control animals that prey on livestock, threatened or endangered species, or are vectors of a communicable disease. The insecticide use is limited to only one SLN label in CA, with sodium cyanide used as a source of hydrogen cyanide gas for quarantine fumigation of surface pests on citrus in shipping containers. There are no dietary, residential, occupational, or aggregate human health risks of concern. Potential bystander risks are low. There are risks to non-target mammalian and avian species as well as *de minimus* risks to terrestrial invertebrates. A "No effect," call was made for all aquatic species, and most reptilian, avian, and mammalian species based on habitat (no proximity to aquatic areas as well as rapid dissipation) as well as size considerations for being unable to trigger the M-44 device. For species that have the potential to trigger M-44 devices, new label language has been developed to minimize this potential, resulting in a "Not Likely to Adversely Affect" finding. This language ensures the certified applicator is aware of the most up to date report of listed species in the application areas, and if a species is potentially in the area, to have species-specific measures to avoid exposure. The language was developed in coordination with USDA APHIS and FWS; FWS is satisfied that the new language is sufficient. Anticipated stakeholder reaction may be negative from the general public and animal welfare groups since this chemical is controversial. The reaction from ranchers is expected to be minimal.

### Sodium Fluoroacetate

Release Interim Decision Amendment. The Interim Decision for sodium fluoroacetate was published in August 2019. The Interim Decision Amendment is being issued to update endangered species label language after completing the Endangered Species Act consultation with Fish & Wildlife Services (FWS). Sodium fluoroacetate is predicide used in livestock protection collars, designed specifically to target coyotes preying on sheep and goats and all products are restricted used pesticides. The main concern for sodium fluoroacetate is acute toxicity via oral and dermal routes of exposure and puncture of the bladders on the collars likely leads to a lethal dose. With the current limited use pattern and limited exposure for sodium fluoroacetate, qualitative human health and ecological risk assessments were performed. There were no human health or ecological risks of concern. Risks of handling the livestock protection collars are mitigated through eighteen label use restrictions and restricted use pesticide status. A "No Effect" determination has been made for all aquatic species, and most reptilian, avian, and mammalian species based on habitat, size and diet considerations for being unable to puncture the livestock protection collar. For the species that have the potential to puncture the collar, new label language will be added to existing labels so these species are extremely unlikely to be exposed, resulting in a "Not Likely to Adversely Affect"

finding. This language ensures the certified applicator is aware of the most up to date report of listed species in the application areas, and if a species is potentially in the area, to have species-specific measures to avoid exposure. The language was developed in coordination with USDA APHIS and FWS; FWS is satisfied that the new language is sufficient. Anticipated stakeholder reaction is minimal.

### Spiromesifen

Release Interim Decision. Spiromesifen is an insect growth regulator/miticide used on agronomic and horticultural crops and landscape ornamentals including residential ornamentals. Spiromesifen is categorized as a Group 23 insecticide, along with spirotetramat and spirodiclofen. It is an effective control for whiteflies, which can transmit plant diseases in many crops. There are potential dietary, residential post-application, aggregate, and occupational handler and post-application risk of concern. Groundwater is the primary contributor to dietary exposure. Any use pattern exceeding an annual application rate of 0.35 lbs ai/A will yield dietary risks of concern (current annual application rates run up to 2.25 lbs ai/A). The Agency also identified potential ecological risks to mammals, pollinators, terrestrial plants, and aquatic invertebrates. Risk mitigation measures include application rate reductions, personal protective equipment, closed mixing/loading systems, prohibition of certain application equipment, re-entry restrictions, spray drift advisory statements, and pollinator and water resource advisories. ***Anticipated stakeholder reaction:*** The Agency narrowed the scope of the application equipment restriction based on a stakeholder comment, and only a few other comments were submitted during the comment period on the proposed decision. The Agency anticipates little stakeholder reaction to the ID; the technical registrant agreed to all the proposed measures.

### Tembotrione

Release Interim Decision. Tembotrione is a member of a group of systemic triketone compounds that inhibit the enzyme *p*-hydroxyphenyl pyruvate dioxygenase (HPPD). Tembotrione is a pre-plant, pre-emergence, post-emergence, and/or post-harvest broad-spectrum herbicide registered for use on corn (field, sweet, pop) to control annual grasses and broadleaf weeds. Section 3 labels allow for application by ground equipment; however, several FIFRA Section 24(c) labels permit aerial applications as well. Tembotrione has no registered residential or non-agricultural (including antimicrobial) uses. There are no human health risks of concern. There are potential ecological risks of concern for mammals, aquatic invertebrates, aquatic and terrestrial plants. Although ecological risks of concern were not identified for birds, the lack of a definitive chronic avian endpoint has been identified as a major uncertainty as predicted upper bound exposures are observed to be within 2x of effect levels observed to result in decreases in mallard growth and reproduction. Required label clarifications include adding a maximum annual application rate to all labels that include any post-harvest applications to eliminate ambiguity as well as updating the glove statement, aquatic invertebrate environmental hazard statements, non-target organism advisory statement, herbicide resistance management language, and mandatory and advisory spray drift management language across all product labels. Little to no impacts are expected from the required label updates. ***Anticipated stakeholder reaction:*** Minimal stakeholder feedback is expected.

### Topramezone

Release Interim Decision. Topramezone is a broad-spectrum systemic herbicide registered for use to control broadleaf and certain grass weeds. The mode of action in plants is inhibition of the 4-

hydroxyphenylpyruvate dioxygenase (HPPD) enzyme. Topramezone can be applied by ground, air, hand-held spray equipment, backpack sprayers, hose-end sprayers, boat-mounted sprayers, and submerged aquatic hoses. Agricultural use sites include field corn (grown for grain, silage, or seed), popcorn (grown for ear, kernel, or seed), sweet corn (grown for ear, kernel, or seed), and sugarcane. Non-agricultural use sites include aquatic vegetation, non-crop ornamentals, African marigolds for lutein and zeaxanthin production, sod farms, residential and recreational turf grass, rights-of-way, and tree plantations. There are no human health risks of concern. There are potential risks of concern for estuarine/ marine invertebrates, mammals, vascular aquatic plants, terrestrial plants, and pollinators. Proposed label clarifications include updated mandatory spray drift language (including medium or coarser droplet size, 3-foot release height for ground applications, and 15 mph wind speed restrictions), advisory spray drift language, non-target organism advisory statement, groundwater and surface water advisory statements, clarification of maximum annual rates, and resistance management language. Little to no impacts are expected from the proposed mitigation. *Anticipated stakeholder reaction is minimal.*